

Effects of *Lactobacillus plantarum* PS128 on Sleep and Physiological Parameters in Self-Reported Insomniacs: a Randomized-Controlled Trial

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Introduction

Insomnia causes inattention and drowsiness affecting daily activities. Recent animal studies have supported that *Lactobacillus plantarum* PS128 (PS128) can reduce the severity of anxiety and depression. However, previous studies did not focus on the sleep quality and mood of humans.

Hypothesis & Aim

We hypothesised that PS128 can enhance sleep quality by ameliorating mood and reducing cortical excitation in self-reported insomniacs.

Aim: To determine whether PS128 reduces the severity of anxiety and depressive symptoms, regulates autonomic nervous system function, and improves sleep quality.

Materials and Methods

Forty participants between 20 and 40 years of age with self-reported insomnia were randomly assigned to two groups, a PS128 group and a control group, in a double-blind trial. Study measures included subjective depressive symptoms, anxiety and sleep questionnaires, and miniature-polysomnography (miniature-PSG) recordings at baseline and on the 15th and 30th days of taking capsules.

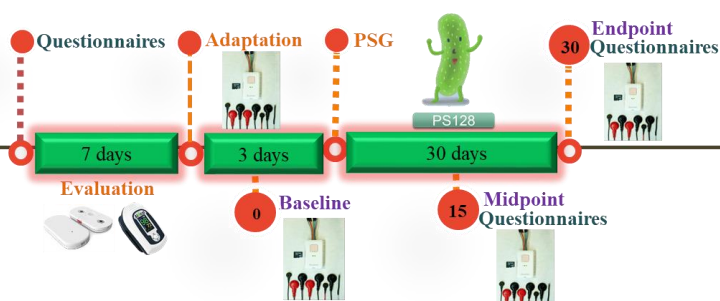


Fig 1. Study schedule. Subjects are conducted miniature-PSG on the adaptation, baseline, midpoint, and endpoint.

Results

Table 1. Baseline demographic data (mean ± SE)

	Control (n=19)	PS128 (n=21)	P value
Male/female	8/11	5/16	
Age (year)	25.47±4.64	26.43±5.95	.58
BMI (kg/m ²)	22.31±2.37	21.60±1.80	.29
PSQI	11.26±2.33	12.33±2.20	.14
ISI	16.74±3.03	17.52±3.49	.45
ESS	9.63±3.59	9.05±4.75	.67
BDI-II	11.21±6.69	13.81±9.64	.33
BAI	10.32±6.98	9.81±7.93	.83

Note. There was no difference in background characteristics by t-test. BMI, Body mass index; PSQI, Pittsburgh Sleep Quality Index; ISI, Insomnia Severity Index; ESS, Epworth Sleepiness Scale; BDI-II; Beck Depression Inventory-II; BAI, Beck Anxiety Inventory.

We divided each group into more specific groups, insomniac and misperception, according to participants' sleep latency and amount of wake after sleep onset. (30 minutes as cutoff point)

All (Con: n=19, PS128: n=21)
Inso (Con: n=9, PS128: n=12) +P<0.05, †<0.01 vs. baseline or 0
Mis (Con: n=10, PS128: n=9) *P<0.05, **P<0.01 vs. Control

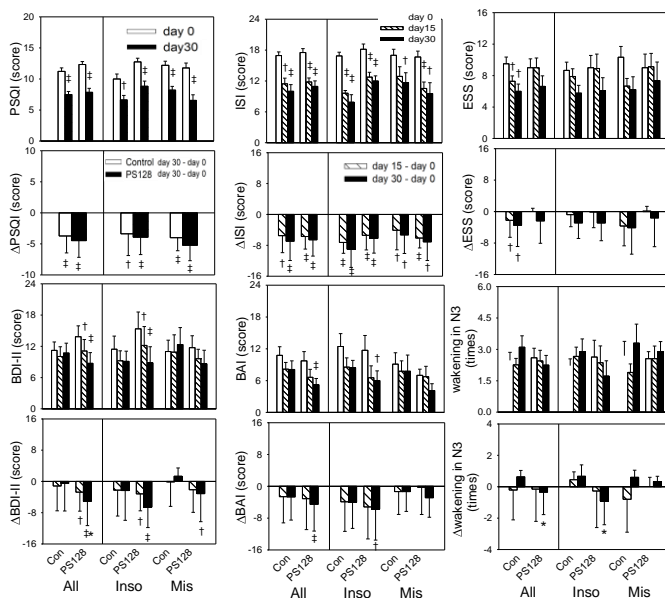


Fig 3. After 4 weeks of treatment, PS 128 and placebo treatment effects on sleep/mood-related scores. Wakening in N3 (Non-rapid eye movement stage 3) was analyzed from sleep staging. Within-group differences were measured by repeated measurement ANOVA. Between group differences were measured by generalised estimating equations. .

1. Within groups analysis, PS128 group and the control group showed significant decrease in PSQI, ISI, BDI-II and BAI scores comparing to baseline.
2. There were a significant decrease between groups in BDI-II and awakenings during deep sleep stage compared to the placebo group.
3. There was no significant differences between groups in HRV analysis.

Conclusion

These findings suggest that daily administration of PS128 may lead to a decrease in depressive symptoms, fatigue level, cortical excitation, and an improvement in sleep quality during the deep sleep stage. Daily consumption of PS128 as a dietary supplement may improve the sleep quality and mood of insomniacs.